

**I Claim:**

1. A method for diagnosing and monitoring Alzheimer's disease in a subject comprising detecting hK6 in a sample derived from the subject.
- 5 2. A method as claimed in claim 1 wherein the hK6 is detected using an antibody reactive with hK6.
3. A method for detecting hK6 associated with Alzheimer's disease in a subject comprising:
  - (a) taking a sample derived from a subject;
  - 10 (b) detecting or identifying in the sample hK6; and
  - (c) comparing the detected amount with an amount detected for a standard.
4. A method for diagnosing and monitoring Alzheimer's disease as claimed in claim 1 comprising:
  - (a) obtaining serum or cerebrospinal fluid from a subject;
  - (b) detecting the amount of hK6 in said serum or cerebrospinal fluid; and
  - 15 (c) comparing said amount of hK6 detected to a standard, where detection of a level of hK6 greater than that of a standard is indicative of Alzheimer's Disease.
5. A method for diagnosing and monitoring Alzheimer's Disease as claimed in claim 1 comprising:
  - (a) contacting a biological sample from a subject with an antibody specific for hK6 which is directly or indirectly labelled with a detectable substance;
  - (b) detecting the detectable substance to quantitate hK6 in the sample;
  - 20 (c) comparing the quantitated level of hK6 to levels obtained for samples from healthy control subjects or from other samples of the subject .
- 25 6. A method for the diagnosis and monitoring of Alzheimer's Disease as claimed in claim 1 comprising
  - (a) incubating a biological sample from a subject with a first antibody specific for hK6 which is directly or indirectly labeled with a detectable substance, and a second antibody specific for hK6 which is immobilized;

- (b) separating the first antibody from the second antibody to provide a first antibody phase and a second antibody phase;
- (c) detecting the detectable substance in the first or second antibody phase thereby quantitating hK6 in the biological sample; and
- (d) comparing the quantitated hK6 with quantitated levels obtained for samples from healthy control subjects or from other samples of the subject.

7. A method as claimed in claim 2 wherein the biological sample is a biological fluid.

8. A method as claimed in claim 2 wherein the biological sample is serum or cerebrospinal fluid.

9. A method as claimed in claim 6 wherein in step (a) the first and second antibodies are contacted simultaneously or sequentially with the biological sample.

10. A method as claimed in claim 2 wherein the antibody is a monoclonal antibody, a polyclonal antibody, immunologically active antibody fragments, humanized antibody, an antibody heavy chain, an antibody light chain, a genetically engineered single chain F<sub>v</sub> molecule, or a chimeric antibody.

11. A method as claimed in claim 5 wherein the detectable substance is alkaline phosphatase.

12. A method as claimed in claim 11 wherein the alkaline phosphatase is detected using a fluorogenic substrate.

13. A method as claimed in claim 12 wherein hK6 is measured using time-resolved fluorescence.

14. A kit for carrying out a method as claimed in claim 4.

15. A kit for carrying out a method as claimed in claim 2 comprising a polyclonal antibody specific for hK6 labeled with an enzyme; and a substrate for the enzyme